UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASTRA AKTIEBOLAG, *et al.*, Plaintiffs, v. ANDRX PHARMACEUTICALS, INC., Defendant.	99-CIV-8926 (DLC) 99-CIV-9887 (DLC)
In re OMEPRAZOLE PATENT LITIGATION	M-21-81 (DLC) MDL Docket No. 1291

ANDRX PHARMACEUTICALS, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT ON DAMAGES

Winston & Strawn LLP

200 Park Ave
New York, NY 10166-4500
Phone: (212) 294-6700
Fax: (212) 294-4700

Attorneys for Defendant
Andrx Pharmaceuticals, Inc.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

STATUTES

TABLE OF AUTHORITIES

Page(s)

OTHER AUTHORITIES

INTRODUCTION

May Plaintiff Astra recover hundreds of millions in damages based solely on Defendant Andrx's mere manufacture of generic omeprazole drug product, which was never used, sold, or offered for sale? The answer, simply, is no.

No case under the Hatch-Waxman Act—the complex statute governing the approval of brand-name and generic drugs and setting forth the process for resolving patent infringement disputes involving them—has ***ever*** awarded damages solely for the manufacture of an infringing generic drug product. To do so would effectively undermine one of the primary purposes of the Act – to quickly get generic drugs to the consumers. Yet this is exactly what Astra attempts to do here. Andrx manufactured generic omeprazole capsules but never sold or used them; instead, the product was destroyed after the courts found Astra's patents valid and infringed. Nevertheless, Astra seeks nearly half a ***billion*** dollars in damages. In fact, as set forth fully below, Astra is entitled to nothing.

FACTUAL BACKGROUND

A. Astra's Original and Revised Complaints

In May 1998, Astra filed a complaint against Andrx alleging that Andrx infringed six U.S. patents by filing an ANDA for the sale of generic versions of 10 mg and 20 mg strength omeprazole. (Andrx's Statement of Undisputed Facts (hereinafter "SUF"[1]) ¶ 14.) The complaint sought a permanent injunction, a declaration delaying the effective date of Andrx's ANDA, costs, and attorney fees under 35 U.S.C. § 285. (SUF ¶ 14.) In July 1999, Astra filed a second complaint, seeking essentially the same relief, alleging that Andrx's ANDA for 40 mg strength

[1] Andrx's citations to the "SUF" are to the accompanying Statement of Undisputed Facts.

omeprazole infringed the same patents, except for U.S. Patent No. 4,255,431.[2] (SUF ¶ 15.) Tellingly, neither complaint sought damages. (SUF ¶ 16.)

After consolidation by the Multi-District Litigation Panel and transfer to this Court (SUF ¶ 17), the complaints were amended to add an allegation that Andrx's ANDA filing was a willful infringement of the '505 and '230 patents and to supplement with a claim that Andrx's ANDA filing infringed Astra's '281 patent. (SUF ¶ 18.) As thus revised, Astra's complaints contained seven "claims for relief,'" with each claim asserting that Andrx's ANDA filing infringed one of Astra's seven patents.[3] The first claim for relief alleged that Andrx, in filing its ANDA, infringed the '505 patent and did so willfully; the second claim contained the same allegations as to the '230 patent. (SUF ¶¶ 17-18.) Again, none of these seven claims requested damages. (SUF ¶ 19.)

B. Andrx's Pre-Commercial Manufacturing and the Bench Trial

In late 2001, in preparation for a district court ruling that its proposed generic product did not infringe the '505 and '230 patents, Andrx began manufacturing generic omeprazole drug product. (SUF ¶¶ 20-27.) Consistent with the Hatch-Waxman Act, this pre-commercial activity would have allowed Andrx to get to market as soon as the patents were cleared. *See* H.R. Rep. No. 98-857, pt. 2, at 6 (Aug. 1, 1984), 1984 U.S.C.C.A.N. 2686, at 2694 ("Section 202 of the bill [now 35 U.S.C. § 271(e)(1)] was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible.").

The Court scheduled a four-phase trial. The first phase focused on infringement and validity of the '505 and '230 patents and began in December 2001. Before then, Astra admitted, "Andrx produced evidence that it had manufactured multiple batches of its ANDA product"—the

[2] The '431 Patent expired April 5, 2001. (SUF ¶ 15.)

[3] The '431 Patent was dropped from Case No. 99-cv-8926.

same conduct that Astra now claims is a "commercial manufacture" entitling it to damages. (SUF ¶ 26; Exh.[4] 10, Dkt.[5] 24, Memo in Support of Its Motion for Leave to Amend at 2 (Nov. 21, 2008).) Though Astra introduced evidence about the manufactured batches, it later insisted that the trial be limited solely to the ANDA, not the manufactured product. (SUF ¶¶ 28-29.) The Court agreed and ruled that the suit would be limited to the ANDA unless Andrx agreed to more discovery. (SUF ¶ 29.) The Court, with Astra's consent, subsequently limited the trial to the ANDA. (*Id.*) At the time, all involved recognized that a challenge to Andrx's manufacturing of generic omeprazole batches could result in another lawsuit. (*Id.*)

C. District Court's Ruling and Appeal

On October 11, 2002, the Court issued a decision finding certain claims of the '505 and '230 patents valid and infringed by Andrx's ANDA. (*Astra Aktiebolag v. Andrx Pharms.*, 222 F. Supp. 2d 529 (S.D.N.Y. 2002), *aff'd*, 84 Fed. Appx. 76 (Fed. Cir. 2003); SUF ¶ 30.) The Court also announced that it would issue final judgment under Rule 54(b), *id.* at 598, which it did later that month. (SUF ¶¶ 30-31.) In doing so, the Court "determine[d]" that it had reached an "ultimate disposition" of the "individual claim[s]" that were the subject of its judgment—that is, the first and second claims. *See Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 7 (1980).

In response to the Court's inquiry about what claims remained unresolved (SUF ¶ 34), Astra responded that it might seek to "to add a claim for damages due to Andrx's commercial manufacture," but that, if it decided to do so, it would "promptly" notify the Court. (SUF ¶ 35.) Nevertheless, Astra said nothing about seeking damages and did not pursue the matter,

[4] Unless otherwise indicated, all exhibits cited herein refer to exhibits to the accompanying Declaration of Peter J. Slawniak in Support of Andrx Pharmaceuticals, Inc.'s Motion for Summary Judgment on Damages.

[5] Unless otherwise indicated, all docket entries refer to *Astra Aktiebolag v. Andrx Pharmaceuticals Inc.*, Case No. 99-cv-9887.

"promptly" or otherwise. Instead, Astra remained mute for five years. (SUF ¶ 36.) During that period, Andrx appealed the Court's final judgment on the first and second claims.

On December 11, 2003, the Federal Circuit concluded that it had jurisdiction over the Rule 54(b) final judgment and affirmed. (*See Astra Aktiebolag v. Andrx Pharms.*, 84 Fed. Appx. 76, 79 (Fed. Cir. 2003); SUF ¶ 32.) In so holding, the appeals court necessarily concluded that Astra's first and second claims were fully resolved by the judgment. *See Aetna Cas. & Sur. Co. v. Giesow*, 412 F.2d 468,470 (2d Cir. 1969) ("the partial adjudication of a single claim is not appealable, regardless of whether there is a Rule 54(b) certificate"). Mandate issued on February 6, 2004. (SUF ¶ 33.)

D. Post-Mandate Motion to Supplement

On July 25, 2007—more than five years after Astra first learned of Andrx's manufacture of generic omeprazole drug product, more than four years after Astra informed this Court that any request to add a claim for damages would be "prompt," and more than three years after the Federal Circuit issued its mandate—Astra advised this Court that it was "entitled to damages" because Andrx "had an inventory of generic omeprazole" that it never sold. (SUF ¶ 36.) Yet Astra still failed to file the requisite motion. More than a year later, Astra sent another letter to the Court containing the same statement. (SUF ¶ 37.) Yet again no motion was filed.

It was not until seven years after Astra first learned of Andrx's manufacturing activity that Astra finally moved for leave to file a second supplemental complaint seeking damages. (SUF ¶ 38.) In its brief, Astra stated it now wished to add a damages request for the "batches disclosed at trial." (SUF ¶ 38; Exh. 10, Dkt. 24, Memo in Support of Its Motion for Leave to Amend at 2 (Nov. 21, 2008).) Astra further explained that it was not seeking to "impose new claims" and was merely "updat[ing]" its pleading to "support damages relief" for the alleged infringement. (SUF ¶ 38.)

The proposed second supplemental complaint dropped the third through seventh claims, which this Court had already rejected, and supplemented the first and second claims, which had been adjudicated in Astra's favor through the final judgment and Federal Circuit's mandate. (SUF ¶ 42.) The new paragraphs alleged that, beginning in October 2001, "Andrx engaged in commercial manufacture of its infringing 'Omeprazole Delayed-release Capsule,'" and that Astra was entitled to "damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C)." (*See* SUF ¶¶ 42-43.)

E. The Court's Order Granting Leave to Supplement

On February 2, 2010, this Court granted Astra's motion for leave to file a supplemental complaint. (Exh. 22, Opinion & Order, Dkt. 35 (Feb. 2, 2010); SUF ¶ 41.) The Court held that the Rule 54(b) judgment—affirmed by the Federal Circuit—did not preclude Astra from seeking another remedy for an adjudged act of infringement by supplementing its complaint with allegations of conduct that Astra was aware of before the trial began. (*Id.* at 13.) The Court further agreed with Astra that the "supplemental allegations [did] not impose new claims" and merely sought "an additional remedy (damages) for the previously pled and adjudged infringement." (SUF ¶ 41.) Andrx's subsequent motion for reconsideration was also denied. (SUF ¶¶ 44-45.)

Astra eventually filed the supplemental complaints on February 8, 2010. (SUF ¶ 42.) The complaints alleged actual infringement by Andrx for "commercial manufacture of [Andrx's] infringing 'Omeprazole Delayed-Release Capsule.'" (*Id.*) As there were no actual sales, Astra did not request lost profits but sought only "a reasonable royalty" under 35 U.S.C. § 271(e)(4)(C). (SUF ¶ 43.)

LEGAL STANDARD

Summary judgment under Rule 56 is appropriate if the moving party demonstrates that there is "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Kirschten v. Research Insts. of Am., Inc.*, No. 94 Civ. 7947(DC), 1997 WL 739587, at *3 (S.D.N.Y. Sept. 24, 1997). Once the moving party has met its burden, the "nonmoving party must come forward with specific facts showing that there is a ***genuine issue for trial***." *Caldarola v. Calabrese*, 298 F.3d 156, 160 (2d Cir. 2002) (emphasis added). The nonmoving party cannot create a triable issue of material fact by presenting evidence that is "merely colorable, conclusory, speculative, or not significantly probative" or that lacks credibility. *Kirschten*, 1997 WL 739587, at *3; *see also Stein v. United States*, No. 07 Civ. 2684, 2009 WL 195953, at *2 (S.D.N.Y. Jan. 28, 2009). Moreover, "[f]actual 'disputes that are irrelevant or unnecessary' cannot defeat a motion for summary judgment," *Loria v. Gorman*, 306 F.3d 1271, 1283 (2d Cir. 2002) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)), nor can mere "conjecture or surmise." *Stein*, 2009 WL 195953, at *2 (quoting *Gottlieb v. County of Orange*, 84 F.3d 511, 518 (2d Cir. 1996)). Further, a court may enter summary judgment before discovery is conducted if "discovery or lack thereof does not impact [the non-moving] party's ability to make [its] argument." *Infostar Inc. v. Worcester Ins. Co.*, 924 F. Supp. 25, 29 (S.D.N.Y. 1996); *see also Caruso v. Candie's, Inc.*, 201 F.R.D. 306, 311 (S.D.N.Y. 2001); *Int'l Minerals & Res. v. Pappas*, 761 F. Supp. 1068, 1079-80 (S.D.N.Y. 1991) (granting partial summary judgment, finding certain damages not available for intentional tort claims); *Pesticide Pub. Policy Found. v. Vill. of Wauconda*, 622 F. Supp. 423, 435 (N.D. Ill. 1985) ("This Court finds that, even if plaintiff had standing to assert a claim for a declaration of entitlement to damages, damages are not available as a matter of law.").

ARGUMENT

Summary judgment that Astra is not entitled to any damages for Andrx's pre-commercial manufacture of its omeprazole ANDA product is appropriate here.

A. Monetary Recovery Is Precluded.

1. Damages Solely for the Manufacture of Generic Product Without Commercial Marketing Are Unavailable As A Matter of Law.

Astra's request for damages for Andrx's act of manufacturing generic omeprazole, without more, is as legally unsupported as it is unprecedented. The request is contrary to the text, purpose, and history of the Hatch-Waxman Act.

a. The Hatch-Waxman Act's language allows damages only for commercial marketing, which did not occur.

The text of the Hatch-Waxman Act requires that Astra's request for damages here be denied. In cases arising under Hatch-Waxman, its provisions supply the rule of decision, not the general provisions of the Patent Act.

Ordinarily, infringement occurs when one "without authority makes, uses, offers to sell, or sells any patented invention ... ." 35 U.S.C. § 271(a); *see also* 35 U.S.C. § 271(b), (c) (defining induced infringement and contributory infringement). The general remedies provisions of the Patent Act govern infringement under these subsections. *See* 35 U.S.C. §§ 283-287, 289. But in 1984, well after these general provisions were on the books, Congress established special rules that apply when companies file an ANDA for approval to market a generic drug product. First, the Hatch-Waxman Act defines infringement as the act of submitting the ANDA. *See* 35 U.S.C. § 271(e)(2). And second, remedies under the Act are set out in 35 U.S.C. § 271(e)(4), separately from the generally applicable patent remedies provisions noted above. *See Pfizer, Inc. v. Apotex Inc.*, 731 F. Supp. 2d 754, 760-61 (N.D. Ill. 2010) (noting Patent Act's "separate provisions for both infringement and remedies" where ANDAs are at issue); *Teva Pharm. Indus.*

Ltd. v. AstraZeneca Pharms. LP, No. 08-cv-4768, 2009 WL 2616816, at *6, n.18 (E.D. Pa. Aug. 24, 2009) ("available remedies" are among differences between infringement actions under § 271(a) and those under § 271(e)).

It is these specific, specially crafted, and separate provisions that the Court must turn to in considering acts of infringement under the Hatch-Waxman Act. *Compare Sanofi-Aventis v. Apotex Inc.*, 748 F. Supp. 2d 293, 296-977 (S.D.N.Y. 2010) (actual commercial sales of drug was conduct that made "'damages or other monetary relief'" available under § 271(e)(4)(C)), *with Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 09-cv-2445, 2010 WL 1372437, at *8 (D.N.J. Mar. 31, 2010) (no infringement claim under § 271(a) when generic manufacturer "ha[d] not yet placed the drug into the market"). Astra acknowledges this: it seeks damages under § 271(e)(4), and it alleges infringement under § 271(e), not under the general provision § 271(a). (*See* SUF ¶¶ 42-43.) Thus, Astra's available remedies are narrow and limited:

> (4) For an act of infringement described in paragraph (2) [submitting an ANDA for approval to market a generic drug]—
>
> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug … , [and]
>
> (C) damages or other monetary relief ***may*** be awarded against an infringer only if there has been ***commercial manufacture***, use, offer to sell, or sale within the United States or importation into the United States of an approved drug …
>
> * * *
>
> The remedies prescribed by subparagraphs (A), (B), (C), and (D) ***are the only remedies which may be granted by a court for an act of infringement described in paragraph (2)*** [submitting an ANDA for

> approval to market a generic drug], except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4) (emphases added). Critically, subsection (C) governing damages is permissive, not mandatory; it states that monetary relief "may" be awarded, not that it must. Further, monetary relief is available "only" in certain circumstances—namely, when there has been "commercial manufacture, use, offer to sell, or sale." *Id.* Just "commercial manufacture" is at issue here, and it is notably absent.

"Commercial manufacture" is not specifically defined in the Hatch-Waxman Act or its regulations. But the Act's legislative history demonstrates conclusively that Congress intended it to mean something more than mere manufacture. *Compare* 35 U.S.C. § 271(a) (providing that one who "makes, uses, offers to sell, or sells" a patented invention infringes the patent). Indeed, the legislative history shows that monetary remedies would become available only if there has been "commercial marketing":

> Proposed subsection (e)(4) makes certain remedies available and exclusive in the event a patent is valid and has been infringed pursuant to subsection (e)(2). … Injunctive relief may be granted to prevent ***commercial marketing*** under an approved ANDA and ***monetary damages or monetary relief are authorized when commercial marketing has begun***.

H.R. Rep. No. 98-857, pt. 2, at 24 (Aug. 1, 1984), 1984 U.S.C.C.A.N. 2686, at 2711 (emphases added); *id.* at H.R. Rep. No. 98-857 at 7, 1984 U.S.C.C.A.N. at 2692 ("The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent."); *see also* H.R. Rep. No. 98-857, pt. 1, at 30 (June 21, 1984), 1984 U.S.C.C.A.N. 2647, at 2679 (stating that an injunction is available "[i]f the infringing party has not begun ***commercial marketing***," but if the infringer "has begun ***commercial marketing*** of the drug, damages and other monetary relief … may be awarded") (emphases added). Thus, for purposes of invoking the damages provision of the Hatch-Waxman Act, Section 271(e)(4)(C),

"commercial manufacture, use, offer to sell, or sale" means "commercial marketing."

Helpfully, the term "commercial marketing" is expressly defined in FDA regulations implementing the Hatch-Waxman Act. It means the introduction into interstate commerce for the purpose of sale:

> Commercial marketing commences with the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer of a drug product, except for investigational use under part 312 of this chapter, but does not include transfer of the drug product for reasons other than sale within the control of the manufacturer or application holder.

21 C.F.R. § 314.107(c)(4). Notably, this definition does not encompass—and in fact would wholly exclude—the mere manufacture of generic drug product. But manufacturing is all that occurred here (SUF ¶¶ 22-27), and so Andrx's actions do not fall within the definition of "commercial marketing."

Because its claims arise (if at all) under the Hatch-Waxman Act, Astra cannot rely on the general statute that imposes liability when one "makes, uses, offers to sell, or sells" a patented invention. 35 U.S.C. § 271(a). Instead, to recover damages, Astra must show "there has been commercial manufacture, use, offer to sell, or sale." 35 U.S.C. § 271(e)(4)(C). There was no "commercial marketing" (SUF ¶¶ 22-27), so the Hatch-Waxman Act precludes recovery.

b. Astra's claim for damages is contrary to the Hatch-Waxman Act's policy and purpose.

While the text of the statute compels the conclusion that actual sales are required before damages can be imposed, the Act's policy and purpose—"which ought to inform its application," *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1362 (Fed. Cir. 2012) (Rader, C.J., dissenting)—confirms that it was intended to shield generic drug manufacturers from damages for activities short of actual commercial marketing. Specifically, while the Hatch-Waxman Act created a remedy for commercial marketing of a drug before patent expiration (or a

finding of patent invalidity or noninfringement), it fell well short of—and in fact ***encouraged***—generic drug manufacturers to engage in pre-commercial activities ***risk free*** in preparation for actual launch.

A full understanding of the policy behind the Hatch-Waxman Act begins with *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984) ("*Bolar*"). There, a generic drug manufacturer, interested in marketing a generic version of Roche's prescription sleeping pill Dalmane® as soon as a patent on the drug expired, began research and development efforts while the patent was still pending. *Id.* at 860. The brand company sued; the generic argued that its activity was protected under a judicially created "experimental use" exception (or another exception that should be created for FDA-required drug testing). *Id.* at 860-62. The Federal Circuit rejected the defense, holding that the experimental-use exception is "truly narrow" and should not be expanded, and that the court should not create a new exception absent Congressional action. *Id.* at 863-65. The effect of the ruling, the court acknowledged, was to add "a *de facto* monopoly of upwards of 2 years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires." *Id.* at 864.

At least in part, Congress's desire to overrule *Bolar* motivated passage of the Hatch-Waxman Act. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990); *see also Momenta Pharms.*, 686 F.3d at 1362-66 (Rader, C.J., dissenting) (discussing legislative history). After *Bolar*, "the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term." *Eli Lilly*, 496 U.S. at 670. To counteract the delay in research and development of relatively inexpensive generic alternatives that resulted from *Bolar*, Congress enacted Hatch-Waxman with the goal "to get generic drugs into the hands of patients at reasonable prices—***fast***." *In re Barr Labs., Inc.*, 930

F.2d 72, 76 (D.C. Cir. 1991) (emphasis added); *AstraZeneca Pharms. LP v. Apotex Corp.*, No. 10-338, 2010 WL 5376310, at *1 (D. Del. Dec. 22, 2010) ("One of the Act's primary purposes was to address impediments to bringing generic drugs to market ***quickly***.") (emphasis added); *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 827 (N.D. Ill. 2004) ("The Hatch-Waxman Act was created to … enabl[e] generic drugs to be marketed more ***cheaply and quickly***.") (emphasis added).

To advance this goal, the Hatch-Waxman Act created a scheme whereby those who planned to market a generic version of a patented drug could conduct development activities before patent expiration—a "safe harbor"[6]—thereby eliminating the *de facto* patent extension. *See* 35 U.S.C. § 271(e)(1); *Teva Pharms. USA*, 301 F. Supp. 2d at 827. The Act also created an "artificial act of infringement," *Eli Lilly*, 496 U.S. at 678—the filing of the ANDA application itself—intended "to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity," *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

In exchange for these provisions, brand-name drug companies received benefits as well: certain exclusivity time periods in which innovator drugs would be on the market free of generic competition (*see, e.g.*, 21 U.S.C. § 355(j)(5)(F)(ii)), extensions of patent terms for delays in FDA approval of such innovator drugs (35 U.S.C. § 156), and a stay on FDA's approval of ANDAs for the first two-and-a-half years of patent litigation (21 U.S.C. § 355(j)(5)(B)(iii)). In this way,

[6] For the purpose of this motion and as represented to this Court, Andrx is not arguing that the manufacture of pre-commercial batches of generic omeprazole was exempt from liability under the safe harbor provision. Rather, Andrx maintains that the safe harbor, along with other provisions, demonstrates that damages liability for pre-commercial activity short of "commercial marketing" is against the policy and purpose of the Act. Andrx reserves the right to later seek judgment on the ground that the safe harbor provision itself excludes the manufacturing activity from damages liability.

the Hatch-Waxman Act "'struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.'" *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 765 (D.C. Cir. 2010) (quoting *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990)).

Astra's efforts here threaten to upset that delicate balance. By seeking to impose damages on Andrx for ***preparing*** to market, but not actually marketing, a generic alternative omeprazole product, Astra's approach would betray the overall purpose of the Act—to facilitate ***fast*** access to cheap prescription drugs.[7] Fearing damages—under Astra's theory here, ***significant*** damages—for merely preparing to commercially launch a generic product, generic manufacturers will put off the manufacturing process until the patents have been cleared. This would be certain to cause non-trivial delays in the availability of generic drugs, thus re-creating the *de facto* patent extension that Hatch-Waxman was designed to eliminate.

Astra's damages theory could have even more dramatic effects in light of changes to the Hatch-Waxman Act that Congress made since Andrx filed its ANDA, changes aimed at ensuring that generic manufacturers would bring their products to market at the earliest opportunity. The Act has always awarded market exclusivity to generic applicants who were first to file ANDAs and challenge the brand company's patents. If successful in litigation, such "first filer" would have the market to itself for 180 days, to the exclusion of other generic competition. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This "first-filer exclusivity," however, was fleeting: it had to be used, or it would be forfeited. Under amendments that Congress passed in 2003, the "first filer" loses

[7] Astra's position seems to be that damages are warranted whenever the manufacture does not qualify for safe-harbor exemption (which Andrx still contends applies here). But the safe-harbor provision of 35 U.S.C. § 271(e)(1) defines infringement, not damages. As demonstrated above, not every infringement is entitled to damages; rather, damages under the Act requires "commercial marketing." For activity of the sort challenged here, Astra's remedy is injunctive relief under 35 U.S.C. § 271(e)(4)(B), which they achieved in the final judgments.

exclusivity if (under certain circumstances) it fails to "market the drug" within 75 days. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa); *Dey Pharm, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012). This punitive measure has the effect of encouraging, if not effectively requiring, generic manufacturers to engage in pre-commercial activities in anticipation of a favorable court decision, by manufacturing sufficient product to immediately engage in commercial marketing when authorized. Waiting would risk forfeiture of "first-filer" exclusivity, if the manufacturing process is lengthy or is met with unforeseen delays, interruptions, or impediments. (As noted below, this pre-commercial manufacturing activity occurs frequently in the industry. *See infra*, Section A.3.)

Either result—delayed market entry due to fear of liability, or inadvertent forfeiture—cannot stand, but both are sure outcomes if Astra's request succeeds. The Court should reject such a theory of liability so inconsistent with the Hatch-Waxman Act's policy and purpose. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003) (rejecting proposed interpretation that was "inconsistent" with Act's "stated purposes"); *AstraZeneca AB v. Mylan Labs., Inc.*, 265 F. Supp. 2d 213, 218 (S.D.N.Y. 2003) (rejecting theory of liability that would create result "contrary to one of the primary purposes" of the Act).

c. Astra's request for damages is contrary to the weight of history.

As with the Hatch-Waxman Act's text and purpose, its history also supports Andrx's interpretation. There is ***no*** precedent under the Hatch-Waxman Act for imposing monetary damages for the type of pre-commercial activity at issue here, even though it has undoubtedly happened before.

Until now, requests for damages against an ANDA filer have been made only where there has been actual commercial marketing, not mere manufacture. *See, e.g.*, *Sanofi-Aventis Deutschland Gmbh v. Glenmark Pharm. Inc., USA*, No. 07-CV-5855, Jury Verdict (Dkt. 319)

(D.N.J. Jan. 14, 2011) (awarding "lost profits" for actual sales made before patents found valid and infringed) (attached as Exh. 27); *Sanofi-Aventis v. Apotex Inc.*, 748 F. Supp. 2d 293, 295-96 (S.D.N.Y. 2010) (awarding damages for actual sales made before patents found valid and infringed, with amount calculated using agreement setting royalty rate), *rev'd in part on other grounds*, 659 F.3d 1171 (Fed. Cir. 2011); *Abbott Labs v. Sandoz, Inc.*, 529 F. Supp. 2d 893, 900-1 (N.D. Ill. 2007) (noting that Sandoz entered the market mid-suit and Abbott amended to allege damages).

But aside from the present case, counsel for Andrx are unaware of any instances in which a brand company sought damages from an ANDA filer for mere manufacture (without more) of generic drug product. In contrast, there are many examples of cases in which the generic manufacture engaged in the same conduct that Andrx is accused of here—manufacture, short of actual sales—and the brand company did ***not*** seek damages. *E.g.*, *Ortho McNeil Pharm., Inc. v. Barr Labs, Inc.*, No. 03-cv-4678, 2009 WL 2182665, at *1 (D.N.J. July 22, 2009) (granting preliminary injunction after generic received FDA approval, noting "there is no dispute that [Barr] has shipped some of the product to distributors"); *Novartis Corp. v. Teva Pharm. USA, Inc.*, No. 04-4473, 2007 WL 1695689, at *2 (D.N.J. June 11, 2007) (denying preliminary injunction, but noting that Teva had already begun shipping orders the same day as FDA approval); *cf. Bolar*, 733 F.2d at 866 ("Counsel for Roche was candid in explaining that he pushed so hard for the harsh [injunctive] relief he did because he thought any money damages [for the experimental use] would have to be nominal.")

Tellingly, even where a court has been aware of the existence of manufactured but unsold product, no court has ever levied damages for the unsold portion of inventory, and litigants have declined to pursue such damages, pointing to the lack of damages. *See In re Apotex, Inc.*, 49

Fed. Appx. 902, 903 (Fed. Cir. 2002) (denying mandamus petition for ANDA filer seeking jury trial; "there can be no damages because no infringing products have been marketed, the only relief that is before the district court is equitable in nature"); *Ortho-McNeil Pharms., Inc. v. Mylan Labs., Inc.*, 267 F. Supp. 2d 545, 549 (N.D. W. Va. 2003) ("because the parties agree that there have been no commercial sales of the alleged infringing levofloxacin tablets, the [damages] remedy of 35 U.S.C. § 271(e)(4)(C) is unavailable").

The result that Astra seeks here, therefore, is unprecedented in the history of the Hatch-Waxman Act. Such a departure from settled history is wholly unwarranted.

2. Astra's Entitlement to Damages Has Not Been Previously Adjudicated.

It is not correct, as Astra asserts, that the Court has already decided the issue of whether damages are available as a matter of law. In fact, the precise issues presented here were neither argued nor decided in connection with Astra's Motion for Leave to File a Supplemental Complaint to assert damages. (*See* SUF ¶¶ 38-40; Dkt. 23-25 (motion), Dkt. 28-29 (opposition), Dkt. 30-31 (reply), Dkt. 35 (opinion and order).)

A review of its brief in opposition to the motion for leave reveals that Andrx did not make the arguments it is making here. Indeed, of the 36-page brief, only some five pages addressed the merits of the damages claim at all—and almost four of those concerned Astra's allegations concerning the "KUDCo Deal." (Exh. 19, Andrx's Memorandum of Law in Opposition, Dkt. 29 at 29-34 (Dec. 2, 2008).) Only a page-and-a-half addressed Astra's claim concerning "commercial manufacture (*id.* at 29-31), and of that, only a single paragraph discussed the fact that no generic product was sold. (*Id.* at 30-31 ("Third, not a single capsule was sold . . .").) Though Andrx briefly argued that there were "no damages" because there were "no sales," that paragraph did not touch on the text, policy, or history of the Hatch-Waxman Act in any way. And in granting Astra's motion, this Court did not discuss those issues either. (*See*

Exh. 22, Opinion & Order, Dkt. 35 (Feb. 2, 2010).) Similarly, neither Andrx's motion to reconsider, nor the Court's opinion denying that motion, dealt with the issues addressed in this motion. (*See* Dkt. 37-38 (motion); Exh. 23, Opinion & Order, Dkt. 40 (Apr. 5, 2010).)

This Court simply has not been briefed on the issues presented here. Astra's contention to the contrary should be rejected.

B. Astra's Request For Monetary Relief Should Be Denied As Improper Double Recovery.

Under the circumstances here, permitting Astra to pursue damages on its first and second claims for relief—the same claims on which Astra obtained a final judgment for injunctive relief—would constitute impermissible double recovery and should thus be denied.

1. Having Obtained Injunctive Relief in a Final Judgment, Astra Cannot Seek Further Relief, Such as Damages, For the Same Claims.

Splitting a single cause of action into a claim for an injunction and a claim for damages is improper. Astra's attempt to do here should be denied.

The Supreme Court has long recognized that a plaintiff is "required to join his legal and equitable claims to avoid the bar of res judicata." *Lytle v. Household Mfg., Inc.*, 494 U.S. 545, 552, 110 S. Ct. 1331, 108 L. Ed. 2d 504 (1990). So too have numerous circuits, holding that it is impermissible to split a claim to obtain double recovery:

> You cannot split a claim into a request for damages and a request for injunction and litigate each in a separate suit. To divide a claim in that way is precisely the vice against which the doctrine of res judicata, in its sense of claim preclusion … is directed.

Creek v. Vill. of Westhaven, 80 F.3d 186, 190 (7th Cir. 1996) (citations omitted); *see also, e.g.*, *Falls Stamping & Welding Co. v. Int'l Union, United Auto. Workers, Aerospace & Agric. Implement Workers of Am.*, 744 F.2d 521, 525 (6th Cir. 1984) ("suits for injunctive relief preclude later claims for damages on the same cause of action."); *Mirin v. Nevada*, 547 F.2d 91,

94 (9th Cir. 1976) (same); *Lambert v. Conrad*, 536 F.2d 1183, 1185-86 (7th Cir. 1976) (dismissing second suit asserting "same cause of action"; that "injunctive relief was sought in the first action and damages are sought in this action is insufficient to distinguish the two actions for purposes of res judicata"); *Clark v. Redeker*, 406 F.2d 883, 885 (8th Cir. 1969) (prior suit for equitable relief barred current suit for damages on same claim; "Plaintiff cannot split a cause of action."). The Second Circuit is among those concluding that res judicata principles prohibit the "improper splitting of a single cause of action into a claim for an injunction and a claim for damages." *Estate of Young*, 810 F.2d 363, 365 (2d Cir. 1987).

Astra's request for damages here is precisely the type of double recovery that these cases prohibit. On claims one and two of its complaint, Astra obtained a final judgment that granted them a permanent injunction barring Andrx from "engaging in commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of its omeprazole formulation . . . on or before April 20, 2007." (SUF ¶ 31.) Now, years later, Astra seeks damages ***on those very same claims.*** There is no material distinction between these facts and those of *Estate of Young*, in which the plaintiff's second suit for damages was barred when plaintiff had already obtained a permanent injunction in a prior final judgment. *Estate of Young*, 810 F.2d at 365.

This is not a case where the new remedy is being sought on new, different claims. In fact, there is no question that Astra seeks damages here on the same claims on which it already obtained injunctive relief. Astra argued as much in its motion for leave to supplement. (SUF ¶ 38; Exh. 10, Astra Memo in Support of Its Motion to Amend, Dkt. 24 at 9 (explaining that Astra was not seeking to "impose new claims"; were merely "updat[ing]" pleadings to "support

damages relief" for the alleged infringement).) And this Court has already ruled that these are not new claims:

> The Court agrees with Astra that the proposed supplemental allegations do not impose new claims. Instead, Astra seeks ***an additional remedy (damages) for the previously pled and adjudged infringement***.

(SUF ¶ 41; Exh. 22, Opinion & Order, Dkt. 35 at 10 (emphasis added); *accord id.* at 12.)[8] Nor is there any question that this is, in reality, a "separate suit." The rule that (non-final) rulings within a case are not res judicata as to other issues in the same lawsuit does not apply where, as here, there has been a final judgment on the claims being adjudicated. (Exh. 13, Final Judgment ¶¶ 1-2 (Oct. 30, 2002) (entering final judgment on the '505 and '230 Patents, respectively).) Moreover, the same final judgment was entered in both Case No. 99-cv-9887 and No. 99-cv-8926, and so the damages claims here are barred by the final judgment entered in the other action. (SUF ¶ 31; Exh. 13, Final Judgment (Oct. 30, 2002); *compare* Dkt. Entry "Judgment" (11/05/2002) in 99-cv-8926 *with* Dkt. Entry "Judgment" (11/05/2002) in 99-cv-9887).[9]

2. This Court Did Not Previously Adjudicate Whether Astra Can Recover Twice on the Same Claims.

The issue of improper double recovery was likewise not argued or decided in connection with the briefing on Astra's Motion for Leave to File a Supplemental Complaint. While Andrx

[8] The usual rule is that double recovery is prohibited on the same claims even in the same suit, and that a plaintiff is required to elect its remedy before final judgment. *E.g.*, *Forster v. Boss*, 97 F.3d 1127, 1129-30 (8th Cir. 1996) (requiring plaintiff to "elect which remedy they want—compensatory damages or the injunction" to prevent double recovery). The Hatch-Waxman Act may change this rubric by specifying the types of remedies available for infringement. *See* 35 U.S.C. § 271(e)(4). But the Act does not override the rule discussed here, that additional remedies cannot be sought in separate suits after claims are adjudicated to final judgment. *Robi v. Five Platters, Inc.*, 838 F.2d 318, 321-22 (9th Cir. 1988) ("Claim preclusion treats a judgment, once rendered, as the full measure of relief to be accorded between the same parties on the same claim or cause of action.").

[9] These entries from 2002 do not have formal Docket Entry numbers.

made (and the Court considered) arguments involving res judicata principles, the issue of improper double recovery was not among them.

In fact, Andrx's arguments were of a wholly different nature: In its opposition to the motion for leave, Andrx argued only that Astra's new allegations were barred by res judicata because they arose from the same transaction as those that had already been adjudicated to final judgment. (Exh. 19, Andrx's Memo. of Law in Opposition, Dkt. 29, at 26-29 (Dec. 2, 2008).) Though Astra itself had argued that the new allegations "arose out of the [same] conduct, transaction or occurrence" that gave rise to the claims already tried (Exh. 10, Astra Memo. in Support of Its Motion to Amend, Dkt. 24, at 15), the Court concluded that Andrx's manufacture of product was a separate, new "event" that nonetheless did not create a new theory of liability but merely a new potential remedy. (Exh. 22, Opinion & Order, Dkt. 35, at 7-9 (Feb. 2, 2010).) Critically, the Court did not consider, much less decide, whether this additional remedy was barred as an impermissible double recovery.

CONCLUSION

For the foregoing reasons, Andrx respectfully requests that the Court grant the motion and enter an order that Astra is entitled to no damages.

Dated: March 8, 2013

By: /s/ Richard F. Lawler
Richard F. Lawler
Lori Van Auken
WINSTON & STRAWN LLP
200 Park Ave
New York, NY 10166-4500
Phone: (212) 294-6700
Email: rlawler@winston.com
Email: lvanauken@winston.com

Michael K. Nutter
Peter J. Slawniak
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601-9703
Phone: (312) 558-5600
Email: mnutter@winston.com
Email: pslawniak@winston.com

Peter E. Perkowski
WINSTON & STRAWN LLP
333 S Grand Ave, Suite 3800
Los Angeles, CA 90071
Phone: (213) 615-1700
Email: pperkowski@winston.com
Attorneys for Defendant Andrx Pharmaceuticals, Inc.